

CSPI Center for
Science in the
Public
Interest

nonprofit
publisher of **Nutrition Action Healthletter**

July 22, 2004

Dockets Management Branch
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20857

Dear Sir or Madam:

Enclosed are the original and three copies of a petition we are submitting. Please docket this document.

Please call me at 202-332-9110 ext. 321 if you have any questions about this document.

Sincerely,



Benjamin Cohen
Senior Staff Attorney

enclosure

2004P-0328

CPI

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Petition to Require Restaurants
To Indicate That the Food
They Serve Contains Trans Fat
From Partially Hydrogenated
Vegetable Oils

Docket No. _____

Submitted by the

CENTER FOR SCIENCE IN THE PUBLIC INTEREST

July 22, 2004

Michael F. Jacobson, Ph.D.
Executive Director
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1875 Connecticut Avenue, NW
Washington, D.C. 20009
202-332-9110

Dockets Management Branch
United States Food and Drug Administration
Department of Health and Human Services
Room 1061
5630 Fishers Lane
Rockville, MD 20857

CITIZEN PETITION

I. PRELIMINARY STATEMENT

The Food and Drug Administration (“FDA”) concluded in July 2003 that 240 to 480 or more lives will be saved each year because of its requirement that beginning in 2006 the amount of trans fatty acids in packaged foods – but not food served in restaurants – be disclosed.¹ However, Americans now consume about 38 percent of their total fat intake in restaurants and other food-service establishments.² The FDA should, therefore, announce that it will require restaurants and other food-service establishments³ to indicate when the food they serve contains trans fats from partially hydrogenated vegetable oils, thereby enabling consumers to select those restaurants that serve foods that do not contain such fats. That announcement would be an interim step until the FDA revokes – as requested in our May 18, 2004, petition (Dkt No. 2004P-0236/CPI) – the legal authority to use partially hydrogenated vegetable oils⁴ (the principal source of trans fat) in foods. The announcement would not be necessary if, as we hope, the FDA takes quick and favorable action on that petition.

¹ 68 Fed. Reg. 41434-41499 (July 11, 2003) (final rule requiring that trans fatty acids be declared in the nutrition label of conventional foods and dietary supplements).

² Lin B, Guthrie J, Frazao E., *Away-From-Home Foods Increasingly Important to Quality of American Diet* (United States Department of Agriculture, Economic Research Service Information Bulletin No. 749, 1999) Table 3 at 5. In 1995, 38 percent of total fat consumption occurred away from home as compared to 18 percent in 1977-78.

³ Section 301 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 331, provides that the FDA only has jurisdiction over food in interstate commerce. However, the Supreme Court has held that most restaurants and food-service establishments sell food in interstate commerce. *See Katzenbach v. McClung*, 379 U.S. 294 (1964) (restaurant in Birmingham, Alabama, affects interstate commerce even though it purchased only \$70,000 a year worth of meat procured from outside Alabama and its customers were not interstate travelers); *Daniel v. Paul*, 395 U.S. 298 (1969) (snack bar in a Little Rock, Arkansas, recreational facility affects interstate commerce, as its advertisements seek out-of-state customers and it serves hot dog and hamburger buns and soft drinks containing ingredients originating outside of Arkansas).

⁴ For stylistic convenience we use the term “vegetable oils” throughout this petition even though, in some contexts, the term includes menhaden oil, which is fish oil, and partially hydrogenated lard.

II. ACTION REQUESTED

The extensive record developed by the FDA as the basis for its 2003 final trans-fat labeling rule for packaged foods negates the need for the FDA to commence a rulemaking to (a) assess the health effects of trans fat and (b) require restaurants⁵ to reveal whether trans fat from partially hydrogenated vegetable oils is an ingredient in the foods they serve. Instead, the Center for Science in the Public Interest⁶ (“CSPI”) requests⁷ that the FDA announce that beginning in January 2006 it will take enforcement action against any restaurant⁸ that does not reveal – either on its menu or on a sign⁹ – that its food has trans fat from partially hydrogenated vegetable oils as an ingredient.¹⁰

As discussed in part VIII. of our May 2004 petition, the FDA should also encourage restaurants to switch to the most healthful alternatives that provide the desired characteristic (recognizing the need for solid fats in some foods), minimizing the use of both partially hydrogenated oils and oils, such as palm oil, high in LDL-cholesterol-raising saturated fat.

III. BACKGROUND

A. Introduction

Our May 2004 petition (in particular, parts III., IV., V., and VI.) discusses in detail both the scientific evidence demonstrating the detrimental impact of partially hydrogenated vegetable

⁵ “Restaurant” should include fast-food restaurants, table-service restaurants, and cafeterias and could exclude street vendors.

⁶ Petitioner Center for Science in the Public Interest, a nonprofit organization based in Washington, D.C., is supported by about 850,000 members in the United States and Canada who subscribe to its *Nutrition Action Healthletter*. CSPI has been working to improve the nation’s health through better nutrition and safer food since 1971.

⁷ This petition is submitted pursuant to 21 C.F.R. 10.25 and 10.30.

⁸ The FDA could initially focus on the 100 largest restaurant chains, which in 2003 accounted for about 52 percent of all restaurant sales. www.technomic.com/ind_facts.html (visited July 13, 2004).

⁹ A restaurant sign or menu notice could say “Some of our foods contain trans fat from partially hydrogenated oils.” Or it could be more explicit: “Only our pastries contain trans fat from partially hydrogenated oils.”

¹⁰ As discussed below in part IV, the enforcement action would assert that such restaurants are violating section 403(a) of the Federal Food, Drug, and Cosmetic Act.

oils on public health and the feasibility of using alternatives, and we incorporate that discussion by reference into this petition.

B. Some United States restaurants have announced they will no longer use partially hydrogenated vegetable oils.

Legal Sea Foods and Ruby Tuesday have announced that they are eliminating partially hydrogenated vegetable oils from all fried foods, and Legal Sea Foods is also requiring its suppliers to eliminate such oils in its desserts and baked goods.

C. United States restaurants doing business in Denmark are complying with Denmark's requirement that the amount of trans fatty acids be limited to two percent of the total amount of fat or oil in the food.

As discussed in more detail in section III.F. of our May 2004, petition, the Danish government announced in March 2003 that as of January 2004 the amount of trans fat from partially hydrogenated oil would be limited to two percent of the total amount of fat or oil in both restaurant and packaged foods. United States restaurant companies doing business in Denmark – such as McDonald's and Burger King¹¹ – are complying with that Danish requirement by eliminating partially hydrogenated vegetable oils.

D. Requiring restaurants to disclose the presence of trans fat could save hundreds of lives a year.

After reviewing the public comments on its 1999 proposed trans-fat labeling rule and having its benefit-cost analysis reviewed by the Interagency Economic Peer Review, the FDA concluded in July 2003 that its final trans-fat labeling rule for packaged foods would save between 240 to 480 deaths year¹² (as compared to its earlier estimate, which was based on different assumptions, of saving 2,500 to 5,600 lives year¹³). As discussed above in Section I., Americans consume only about 62 percent of their fat from packaged foods. Assuming that that ratio also applies to trans fat, then a simple extrapolation from the FDA's 2003 estimate for the lives saved from the trans-fat labeling of packaged foods means that an additional 147 to 294 lives would be saved annually by requiring the disclosure of trans fat in restaurant foods.¹⁴

¹¹ Other United States restaurant companies, such as KFC, also do business in Denmark.

¹² 68 Fed. Reg. at 41488.

¹³ 64 Fed. Reg. at 62772.

¹⁴ That is probably an underestimate considering how much partially hydrogenated oil is used by so many restaurants. Using FDA's 1999 estimate, restaurant labeling would be predicted to save 1,532 to 3,432 additional lives per year. Considering that the packaged-food labeling rule

In 2003, the FDA also calculated the dollar value of the health benefits from requiring the disclosure of the amount of trans fat in packaged foods, looking at both the dollar value of the extension of longevity and the savings in medical costs associated with reductions in nonfatal cases of coronary heart disease. Using a discount rate of 3 percent and depending on which assumptions are used, the FDA estimated the cumulative total of the benefits of its packaged-foods labeling rule over 20 years at \$13.1 billion to \$26.8 billion.¹⁵ A simple extrapolation of the FDA's 2003 estimate yields discounted additional benefits over 20 years from restaurant disclosure of \$8.0 billion to \$16.4 billion.¹⁶

E. Almost two-thirds of United States consumers think it is important to know whether a restaurant's food contains trans fat from partially hydrogenated vegetable oils.

A recent nationally representative telephone survey of 1,013 randomly chosen adults (attached) found that 66 percent said that restaurants should indicate whether the food that they serve contains trans fat; 31 percent answered in the negative, and 3 percent had no opinion.¹⁷

is having a greater effect on product reformulation than predicted, all of those estimates are likely to be underestimates.

¹⁵ Table 12 at 68 Fed. Reg. 41490. In its 1999 benefit-cost analysis of its proposed trans-fat labeling rule, the FDA used a discount rate of 7 percent. Table 25 at 64 Fed. Reg. 62786. John F. Morrall, III, of the Office of Information and Regulatory Affairs of the Office of Management and Budget, estimates that requiring packaged-food labels to disclose the amount of trans fat costs only \$3,000 per life saved, which he concludes is almost two orders of magnitude more efficient than 76 other final regulations that have been enacted. J. F. Morrall, III, "Saving Lives: A Review of the Record," *The Journal of Risk and Uncertainty*, 27:3; 221-237 (2003).

¹⁶ In 2002 there were approximately 526,000 restaurants in the United States (of which about 27 percent were owned by the 100 largest chains). www.technomic.com/ind_facts.html (visited July 13, 2004). At a cost per sign of, say, \$50, the total initial cost for the signs called for by our proposal would be about \$26 million. Those signs might have to be replaced every couple of years. Also, the use of more-healthy oils might (or might not) cost more.

¹⁷ The survey was conducted on July 14-18, 2004 by TNS Intersearch. The question asked was: "The U.S. Food and Drug Administration, or FDA, has concluded that consuming a particular fat – called trans fat – increases the risk of heart disease. Trans fat is present in some of the shortenings used for frying foods or for baking. The FDA is requiring packaged foods to disclose the amount of trans fat in each serving. However, the FDA is not requiring restaurants to disclose any information about trans fat. In your opinion, should restaurants indicate whether the food that they serve contains trans fat?"

IV. THE FDA HAS AMPLE LEGAL AUTHORITY TO REQUIRE RESTAURANTS TO REVEAL WHEN TRANS FAT FROM PARTIALLY HYDROGENATED VEGETABLE OILS IS AN INGREDIENT IN THEIR FOODS.

A. For restaurant food, “labeling” under the Federal Food, Drug, and Cosmetic Act includes menus, signs, placards, and posters.

Section 201(m) of the Federal Food, Drug, and Cosmetic Act (“FFDCA”), 21 U.S.C. 321(m), defines “labeling” to mean, in pertinent part, “other written, printed, or graphic matter accompanying such article.” In *Public Citizen, Inc. v. Shalala*, 932 F. Supp. 13 (D.D.C. 1996), the federal District Court held that, in the context of restaurants, labeling includes restaurant menus as well as signs, placards, and posters (the FDA had asserted – in its 1993 final rule implementing the Nutritional Labeling and Education Act – that restaurant labeling did not include menus).

B. Section 403(a) of the Federal Food, Drug, and Cosmetic Act applies to the labeling of restaurant food as well as packaged foods.

Subsection 403(a)(1) of the FFDCA, 21 U.S.C. 343(a)(1), provides that a food is misbranded if “its labeling is false or misleading in any particular.” In only two of the nine current subsections of section 403 dealing with labeling – subsections 403(q)(5)(A) and 403(r)(5)(B)¹⁸ – did Congress exempt restaurants and other food-service establishments from the labeling requirements of the statute.¹⁹

Another example of Congress’s indicating that a subsection of section 403 does not apply to restaurants involves the Saccharin Study and Labeling Act, P.L. 95-203, which was passed in 1977 (part of this law was repealed in 1996 and the remainder was repealed in 2000). It amended section 403 of the FFDCA to require, in part, food label or labeling in retail establishments to include a statement about the risks of saccharin. The congressional conference committee on this

¹⁸ Subsection 403(q)(5)(A) exempts restaurants from all mandatory nutrition information, and subsection 403(r)(5)(B) exempts restaurants from certain requirements dealing with nutrient-content and health claims.

¹⁹ Congress also effectively exempted most restaurant food from the six subsections of section 403 that deal only with “labels.” Labels are defined in section 201(k) of the FFDCA as “a display of written, printed, or graphic matter upon the immediate container of any article,” and so those six subsections clearly do not apply to restaurants (except for take-out food – such as pizza in a box). See subsections 403(c)(label for imitation foods), (e)(label containing name and place of firm and weight of contents), (g)(label bearing name of food with a standard of identity), (h)(label showing food falls below standard of quality), (i)(label showing the name of the food and its ingredients), and (j)(label showing vitamins and minerals for foods for special dietary uses).

legislation said “that none of the provisions with respect to signs in retail establishments are to apply to restaurants or similar food service establishments.” H.R. Rept. 95-810, 95th Cong. 1st sess. (1977) at 12.

In addition, Congress specified, in section 405 of the FFDCA, 21 U.S.C. 345, two additional exemptions from the labeling requirements of the statute. Neither of those two exemptions refers to restaurants.²⁰

It is a general rule of statutory interpretation “that when a statute lists several specific exceptions to the general purpose, others should not be implied.” *Sierra Club v. Environmental Protection Agency*, 719 F.2d 436, 453 (D.C. Cir. 1983), *cert. denied*, 468 U.S. 1204 (1984)(citing *A.H. Phillips, Inc. v. Walling*, 324 U.S. 490 (1945)). That judicial principle was applied by the federal District Court in 1996 when it construed the two subsections of section 403 of the FFDCA that explicitly exempt restaurants from some of the mandatory nutrition information requirements of the FFDCA. *Public Citizen, Inc. v. Shalala, op.cit.* at 15.

Thus, no exemption for restaurant food should be implied for the labeling misbranding provision of subsection 403(a).

C. Restaurant food is “misbranded” when its labeling fails to reveal that the food contains as an ingredient trans fat from partially hydrogenated vegetable oils because such information is “material” within the meaning of the Federal Food, Drug, and Cosmetic Act.

Section 201(n) of the FFDCA, 21 U.S.C. 201(n), says that “in determining whether the labeling...is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also *the extent to which the labeling...fails to reveal facts material in the light of such representations or material with respect to consequences which result from the use of the article to which the labeling ... relates ... under such conditions of use as are customary or usual.*” (emphasis added).

The presence of trans fat in restaurant food is clearly a “material” fact because it is largely unknowable by the consumer and can have severe “consequences” to health. The FDA has already determined, in its final rule requiring disclosure of the amount of trans fat in packaged foods, that the consumption of foods containing trans fat increases the risk of coronary heart disease. As discussed above in section III.D., requiring the disclosure of the presence of trans fat in restaurant food could save hundreds of lives a year. Moreover, as discussed above in section

²⁰ Section 405 provides, in pertinent part, that “The Secretary shall promulgate regulations exempting from any labeling requirements of this Act (1) small open containers of fresh fruits and fresh vegetables and (2) food which is in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed...”

III.E., survey research indicates that consumers consider it important—“material”—to know whether a restaurant food contains trans fat from partially hydrogenated oils.²¹

While we strongly advocate the disclosure by chain restaurants of a modicum of nutrition information on menus and menu boards,²² we recognize that the amendments to the FFDCFA made by the Nutrition Labeling and Education Act specifically exempt restaurants from nutrition-labeling requirements in most situations.²³ However, requiring disclosure of the presence of trans fat from partially hydrogenated oil is different from disclosing other nutrients that contribute to health problems. First of all, we are asking the FDA to require disclosure of the use of an ingredient, not to provide quantitative labeling of a nutrient. Furthermore, consumers have heard for several decades that meat, whole milk, and cheese are high in saturated fat; that large meals are high in calories; and that restaurant meals and packaged foods are frequently high in salt. However, consumers do not have a general knowledge that most restaurants cook foods in trans-rich vegetable oils and certainly have no way of perceiving whether a particular restaurant prepares foods with partially hydrogenated or nonhydrogenated vegetable oils. Unlike certain ingredients of a restaurant meal, the consumer cannot detect the presence of trans fat either by observing the menu or menu-board (that a meal contains meat, butter, or cheese would indicate the presence of saturated fat) or by tasting the food (as in the case of salt). Furthermore, as indicated by the experience of Legal Sea Foods, restaurants could both change their cooking practices to avoid the use of partially hydrogenated oil and identify suppliers whose foods are prepared without partially hydrogenated oil.

Thus, restaurant food that fails to disclose that one of its ingredients is trans fat from partially hydrogenated vegetable oils violates sections 403(a) and 201(n) of the FFDCFA.

V. ENVIRONMENTAL IMPACT

The action requested is subject to a categorical exclusion under 21 C.F.R. 25.30 and

²¹ It is, of course, also important for consumers to know about other food nutrients. Thus, section 403(q)(1) of the FFDCFA, 21 U.S.C. 343(q)(1), requires disclosure for packaged foods of the amount per serving of calories, total fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, dietary fiber, and total protein. However, in section 403(q)(5)(A)(i) of the FFDCFA Congress specifically exempted from disclosing that information “food which is served in restaurants or other establishments in which food is served for immediate consumption or which is sold for sale or use in such establishments.”

²² The House, Senate, and several state legislatures are considering bills that would require calories to be listed on menu boards and calories, sodium, and saturated+trans fat to be listed on printed menus.

²³ Subsections 403(q)(5)(A) and 403(r)(5)(B) of the FFDCFA, 21 U.S.C. 343 403(q)(5)(A) and 403(r)(5)(B).

25.32 and therefore does not require the preparation of an environmental assessment.

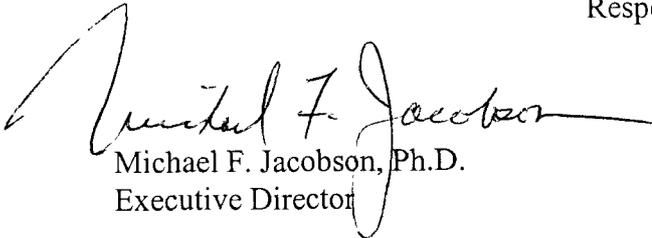
VI. ECONOMIC IMPACT

No statement of the economic impact of the requested action is presented because none has been requested by the Commissioner.²⁴

VII. CERTIFICATION

The undersigned certify that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,



Michael F. Jacobson, Ph.D.
Executive Director



Benjamin Cohen
Senior Staff Attorney

attachment: Table 1 of July 19, 2004 TNS telephone survey

²⁴ 21 C.F.R. 10.30(b).



***“Restaurant Disclosure Of
Trans Fat In Foods”
Standard Banner 1***

Prepared For :

Michael Jacobson

Center for Science in the Public
Interest

Week 28 July 14-18, 2004

EXPRESS

TNS
 July 19, 2004
 EX-27578

Table 1
 trial. The U.S. Food and Drug Administration, or FDA, has concluded that consuming a particular fat - called trans fat - increases the risk of heart disease. Trans fat is present in some of the shortenings used for frying foods or for baking. The FDA is requiring packaged foods to disclose the amount of trans fat in each serving. However, the FDA is not requiring restaurants to disclose any information about trans fat. In your opinion, should restaurants indicate whether the food that they serve contains trans fat?

BASE: Total Respondents

	Sex		Age					Income				Region				Race			Inter net		
	Total	Male	Fe- male	18-34	35-44	45-54	55-64	65+	<\$25k	\$25k- 34.9k	\$35k- 49.9k	\$50k- 99.9k	\$100k+	North- east	North Cntrl	South	West	White	Black	Other	Yes
	(A)	(B)	(C)	(D)	(E)	(F)	(G)	(H)	(I)	(J)	(K)	(L)	(M)	(N)	(O)	(P)	(Q)	(R)	(S)	(T)	(U)
Total Unweighted	1013	504	509	216	174	203	178	238	211	126	136	249	99	194	238	369	212	793	68	101	675
	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
Total Weighted	999	482	518	314	188	207	134	154	207	124*	129*	258	96*	183	233	373	211	682	102*	178*	687
	100	100	100	100	100	100	100	100	100	100*	100*	100	100*	100	100	100	100	100	100*	100*	100
Yes	656	299	357	220	124	148	84	78	133	90	102	179	47	120	160	252	124	415	85	138	454
	65.6	62.1	68.9b	70.2H	65.5H	71.4H	62.8H	50.9	64.2M	72.2M	79.2I	69.5M	48.7	65.6	68.7q	67.6q	58.7	60.9	82.9R	77.5R	66.0
No	307	165	142	87	59	58	43	60	65	33	25	75	48	53	64	109	82	242	15	39	219
	30.8	34.2C	27.5	27.7	31.5	28.0	32.2	38.8DF	31.5K	26.9	19.1	29.2k	50.3I	29.1	27.3	29.2	38.7n	35.5S	14.7	22.2	31.8
													JKL				Op	T			
Don't know	33	17	16	7	5	1	6	14	8	1	2	2	-	8	8	11	5	22	3	1	14
	3.3	3.4	3.1	2.2	2.5	0.6	4.8F	8.9DEF	3.9lm	0.8	1.7	0.9	-	4.4	3.6	3.0	2.6	3.2	2.4	0.3	2.1
Refused	3	1	2	-	1	-	*	2	1	-	-	1	1	1	1	1	-	2	-	-	1
	0.3	0.2	0.4	-	0.5	-	0.1	1.4df	0.3	-	-	0.4	1.0	0.8	0.4	0.2	-	0.3	-	-	0.1

Proportions/Means: Columns Tested (5%, 10% risk level) - B/C - D/E/F/G/H - I/J/K/L/M - N/O/P/Q - R/S/T
 * small base